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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/771,382

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Ian Richard Anselm Peak

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04/01/2010

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

NOTIFICATION DATE

DELIVERY MODE

04/01/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@panitchlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 09/771,382	<b>Applicant(s)</b> PEAK ET AL.	
	<b>Examiner</b> VANESSA L. FORD	<b>Art Unit</b> 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/6/10.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33,34,49-52,54,55 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 33,34,49-52,54,55 and 57-60 is/are allowed.
- 6) ☒ Claim(s) 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### FINAL ACTION

1. This Office Action is responsive to Applicant's response filed November 6, 2009. Claims 1-32, 35-48, 53, 56 and 62 are canceled. Claims 33-34, 49-52, 54-55 and 57-61 are under examination. Claims 33-34, 49-52, 54-55 and 57-60 are allowed.

### ***Rejection Maintained***

2. The rejection of claim 61 under 35 U.S.C. 103(a) as unpatentable over is Peak et al (*WO 99/31132, published June 1999*) is maintained for the reasons set forth on pages 2-3, paragraph 2 of the previous Office Action.

The rejection is reiterated below:

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 61 is rejected under 35 U.S.C. 103(a) as unpatentable over Peak et al (*WO 99/31132, published June 1999*).

Claim 61 is drawn to an isolated protein having at least 90% sequence identity to SEQ ID No:23 or SEQ ID No:35 wherein the isolated protein is not a wild-type NhhA polypeptide and wherein the isolated protein is immunogenic.

Peak et al teach proteins from *Neisseria meningitidis* and immunogenic compositions as well as pharmaceutical compositions containing the polypeptide (see the Abstract and pages 29-30). Peak et al defines the term "fragment" to include deletion mutants and small peptides, for example of at least 6, preferably at least 10 and more preferably at least 20 amino acids in length, which comprise antigenic determinants or epitopes (page 11). Therefore, Peak et al teach NhhA polypeptides that are not the wild-type. Peak et al teach a *N. meningitidis* protein ORF40-1 protein (SEQ ID NO:5) that has the amino acid sequence that is 98.1% identity to SEQ ID NO:23 and a *N. meningitidis* protein ORF40-1 protein (SEQ ID NO:5) that has the amino acid sequence that is 99.3% identity to SEQ ID NO:35. Peak et al contemplate

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polypeptides that are fragments or variants or derivatives of the polypeptide set forth in SEQ ID No. 5 (page 3).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make polypeptides that include antigenic determinants or epitopes of NhhA polypeptides of the invention because Peak et al contemplate fragments or variants or derivatives of NhhA polypeptides and defines the term "fragment" to include deletion mutants and small peptides, for example of at least 6, preferably at least 10 and more preferably at least 20 amino acids in length, which comprise antigenic determinants or epitopes (page 11). Thus, Peak et al teach NhhA polypeptides having at least 90% sequence identity to SEQ ID No:23 or SEQ ID No:35 wherein the isolated protein is not a wild-type NhhA polypeptide and wherein the isolated protein is immunogenic.

#### Applicant's Arguments

Applicant urges that Peak et al do not teach an ORF 40-1 protein. Applicant urges that presumably the Examiner is referring to SEQ ID No. 5 to compare the claimed proteins as set forth as SEQ ID NOs. 23 and 35. Applicant urges that SEQ ID NO.5 of Peak et al is a wild-type Nhh protein. Applicant urges that the Examiner seems to be comparing a sub-region of the full-length sequence (e.g. SEQ ID NO.5) with the entire respective sequences of SEQ ID NOs, 23 and 35 in hindsight. Applicant urges that Peak et al do not teach or suggest the particular sub-region of any of the protein sequences therein that the Examiner is comparing with SEQ ID Nos. 23 and 35.

#### Examiner's Response to Applicant's Arguments

Applicant's arguments filed November 6, 2009 have been fully considered but they are not persuasive.

Claim 61 is drawn to an isolated protein having at least 90% sequence identity to SEQ ID No:23 or SEQ ID No:35 wherein the isolated protein is not a wild-type NhhA polypeptide and wherein the isolated protein is immunogenic. Therefore, the claim encompasses proteins that are variants of the amino acid sequences set forth in SEQ ID Nos. 23 and 35. Peak et al teach variants of proteins (e.g. SEQ ID No.5). Peak et al teach that variants will be at least 75% homologous, more suitably at least 80%, preferably at least 85% and most preferably at least 90% homologous to the basic sequences as for example shown in SEQ ID Nos. 2, 5, 7, 9, 11, 12, 15, 17, 19 and 21 (page 13). Peak et al teach that homology is defined as the percentage number of amino acids which are identical or constitute conservative substitutions (page 13). Thus, Peak et al teach amino acid sequences variants that are at least 90% of SEQ ID No. 5, which encompasses variant amino acid sequences that are 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98% or over 99% identical to SEQ ID NO.5. One of ordinary skill in the art would reasonably conclude with an expectation of success that Peak et al teaches variants of SEQ ID No.5 that are at least 90% identical to the claimed amino acid sequences set forth in SEQ ID Nos. 23 and 35. It should be remembered that variant sequences of SEQ ID No.5 are *not* wild-type Nhh proteins and are large enough to be immunogenic. Thus, they would read on the invention disclosed in claim 61.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was

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within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Therefore, the variants of SEQ ID No.5 as set forth in Peak et al render the inventions set forth in claim 61 as obvious.

### ***Status of Claims***

3. Claims 33-34, 49-52, 54-55 and 57-60 are allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Conclusion***

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/

Primary Examiner, Art Unit 1645

March 24, 2010

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